

REMARKS

Claim 9 has been amended to correct an informality. Applicant respectfully requests entry of the amendment since the amendment places the claim in condition for allowance and does not require further examination by the Examiner.

Claims 1-4, 8, 12, 14, 18, 22-32, 36, 38, 40, 42, 46 and 50-54 stand rejected under 35 USC 102(e) as being anticipated by Florio et al. ("Florio"). Applicant respectfully traverses this rejection. In the previous response, Applicant articulated distinctions between the present claims and the reference cited thus indicating that the reference was insufficient to anticipate the claims. The content of the previous response is incorporated by reference herein in its entirety.

The Examiner has replied by indicating that the reference discloses the use of morphological analysis to determine whether capture has occurred, citing, for example, paragraph 103 wherein Florio states "One or more of these IEGM characteristics are then used by the method of the present invention, as it will be described below, in order to distinguish between single-chamber capture, biventricular capture, or complete loss of capture, based on comparisons made between an acquired IEGM during normal stimulation and the known characteristics of the IEGM during the three capture situations." As will be set forth below, the Examiner's interpretation of the reference does not provide a basis for anticipation.

As the Examiner is well aware, in order for a reference to anticipate a claim, that reference must teach each element of the properly construed claim. Contrary to the Examiner's assertions, Florio does not deliver a pacing pulse to a given chamber, sense within that chamber and determine, based upon morphological characteristics whether the pacing pulse captures that chamber of the heart as in, e.g., claim 1. As such, the rejection is improper and must be withdrawn.

The Applicant maintains that, as stated in the previous response, Florio does not use morphological analysis to determine whether capture occurs or not. Rather, when capture is known to occur, morphological characteristics of the IEGM are analyzed to determine if the capture signal represents single chamber capture or biventricular chamber capture. Since Florio teaches biventricular stimulation through a bifurcated connector, a stimulation pulse will either result in a complete loss of capture or capture of one or both ventricles. At paragraph 104, Florio states "In a preferred embodiment, IEGM characteristics representing the typical morphologies of the IEGM during (1) single-chamber capture and (2) bi-ventricular capture are stored in memory 94." Florio goes on to describe methods for acquiring the typical morphologies of the IEGM during single-chamber capture and biventricular capture. Nowhere in the disclosure does Florio teach or suggest storing typical morphologies of the IEGM during complete loss of capture.

At paragraph 64, the reference teaches that capture is determined based upon the timing of a subsequently sensed response after a stimulation pulse. "The microcontroller 60 detects a depolarization signal during a window following a stimulation pulse, the presence of which indicates that capture has occurred." One of the subsequently-listed IEGM characteristics relied upon for distinguishing between single-chamber capture, biventricular capture, and complete loss of capture is a "time interval 177 between the ventricular stimulation pulse and any subsequently detected events." The reference explains the use of the known prior art technique of generating a pacing pulse and noting the time until, in this case, a ventricular event is sensed. This type of capture detection was discussed extensively in Applicant's previous remarks, which are incorporated by reference, and does not represent determining capture based on one or more morphological characteristics of the IEGM signal. This type of evoked response measurement is the basis for which capture is detected by Florio, and, once capture is detected, then the IEGM morphological characteristics are evaluated to determine if one or both ventricles were

captured. The Florio capture detection method is therefore distinct from the claimed invention, for the same reasons as previously established.

In the claimed invention, as in claim 1 for example, a pulse is delivered to a given chamber and that chamber is sensed for a signal. That signal is then subjected to a morphological analysis from which it may be determined whether capture occurred or not. Thus, the claimed invention distinguishes between capture and loss of capture based on morphological analysis.

The terminology "morphological characteristics" must be given a proper meaning in the context of the claims and in the context of the specification. Merely detecting the time between a stimulation pulse and a detected depolarization is not a morphological analysis. Thus, Florio may detect capture based on IEGM characteristics (timing from stimulation pulse to depolarization) but does not teach detecting capture based on IEGM morphological characteristics. The present claims provide a system where the morphological characteristics of a signal are evaluated to determine if the previous pacing pulse captured. This occurs regardless of the relative timing. That is, a capture pulse may lead to a sensed signal that, based on timing, would appear not to have been evoked. By determining the morphology of the signal, the present invention is able to make that determination.

The remaining claims are allowable for the same or similar reasons. The rejections presented under 35 USC 103(a) are likewise unsupportable and the additional references cited fail to remedy the deficiencies noted. No reference or combination of references teaches determining the morphology of a sensed signal to determine capture, based upon a properly construed definition of "morphological characteristics" or similar terminology as used in the specification and claims.

As such, the present claims are in condition for allowance and notice of the same is requested. Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution.

Respectfully submitted,

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/Daniel G. Chapik/
Daniel G. Chapik
Reg. 43,424
Telephone: (763) 514-3066
Customer No. 27581